

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON**

NICHOLAS COOK, Individually and on  
Behalf of All Other Persons Similarly Situated, )  
Plaintiff, )  
v. )  
ATOSSA GENETICS, INC., STEVEN C. )  
QUAY, CHRISTOPHER BENJAMIN, KYLE )  
GUSE, SHU-CHIH CHEN, JOHN )  
BARNHART, STEPHEN J. GALLI, )  
ALEXANDER CROSS, H. LAWRENCE )  
REMMEL, DAWSON JAMES SECURITIES, )  
INC., VIEWTRADE SECURITIES, INC., and )  
PAULSON INVESTMENT COMPANY, INC. )  
Defendants. )

Civil Action No.: )  
CLASS ACTION COMPLAINT )  
JURY TRIAL DEMANDED )

Plaintiff Nicholas Cook (“Plaintiff”), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities

## CLASS ACTION COMPLAINT

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1 and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding  
 2 Atossa Genetics, Inc. (“Atossa” or the “Company”), analysts’ reports and advisories about the  
 3 Company, and information readily obtainable on the Internet. Plaintiff believes that substantial  
 4 evidentiary support will exist for the allegations set forth herein after a reasonable opportunity  
 5 for discovery.

6 **NATURE OF THE ACTION**

7 1. This is a federal securities class action on behalf of a class consisting of all  
 8 persons other than defendants who purchased or otherwise acquired Atossa shares between  
 9 November 8, 2012 and October 4, 2013, both dates inclusive (the “Class Period”), and/or who  
 10 acquired Atossa shares pursuant or traceable to Atossa’s false and misleading Registration  
 11 Statement and Prospectus in connection with its November 8, 2012 initial public offering  
 12 (“IPO”), seeking to recover damages caused by defendants’ violations of the federal securities  
 13 laws and to pursue remedies under §§ 11, 12(a)(2) and 15 of the Securities Act of 1933 (“1933  
 14 Act”), and under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange  
 15 Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top  
 16 officials.

17 2. Atossa is a development-stage healthcare company. The Company is focused on  
 18 the commercialization of cellular and molecular diagnostic risk assessment products and related  
 19 services for the detection of pre-cancerous conditions that could lead to breast cancer, and on the  
 20 development of second-generation products and services.

21 3. The Food, Drug and Cosmetic Act and the U.S. Food and Drug Administration  
 22 (“FDA”) play a major role in the oversight of the Company’s products. Section 510(k) of the  
 23 Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify the  
 24 FDA of their intent to market a medical device at least 90 days in advance. This is known as  
 25  
 26

1 Premarket Notification - also called PMN or 510(k). This allows the FDA to determine whether  
2 the device is equivalent to a device already placed into one of the three classification categories.  
3 Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been  
4 classified can be properly identified. Specifically, medical device manufacturers are required to  
5 submit a premarket notification if they intend to introduce a device into commercial distribution  
6 for the first time or reintroduce a device that will be significantly changed or modified to the  
7 extent that its safety or effectiveness could be affected. Such change or modification could relate  
8 to the design, material, chemical composition, energy source, manufacturing process, or intended  
9 use.

10       4. Despite feigning compliance with FDA rules and regulations, throughout the  
11 Class Period, Atossa in fact failed to comply with various FDA rules and regulations and misled  
12 investors regarding its compliance with FDA rules and regulations, including Section 510(k),  
13 Good Manufacturing Practices regulations, and fair and honest marketing practices.

14       5. For instance, on November 9, 2012, Atossa filed its Prospectus for the IPO, which  
15 forms part of the Registration Statement that became effective on November 8, 2012. Pursuant  
16 to the IPO, 800,000 shares of Atossa were sold at a price of \$5.00 per share, raising  
17 approximately \$3,100,000 in net proceeds for the Company after underwriting discounts,  
18 commissions, and fees. Atossa used the net proceeds from the IPO, among other things, to  
19 expand its cytology and molecular diagnostics laboratory and fund the manufacture of Mammary  
20 Aspirate Specimen Cytology Test ("MASCT") System units.

21       6. In Atossa's Prospectus the Company stated that its products were "cleared" by the  
22 U.S. Food and Drug Administration ("FDA") for, "collect[ing] fluid samples from the breast  
23 milk ducts, where, according to the National Cancer Institute, over 95% of breast cancers arise."

1 The Company further stated regarding its ForeCYTE and MASCT products:

2       The ForeCYTE Breast Health Test, launched in December 2011, provides  
 3 personalized information about the 10-year and lifetime risk of breast cancer for  
 4 women between ages 18 and 65. It involves collecting a specimen of nipple  
 5 aspirate fluid, or NAF, using our patented, FDA-cleared *Mammary Aspirate*  
*Specimen Cytology Test*, or MASCT, System (*our MASCT System received 510(k)*  
*clearance from the FDA in 2003*).

6 [Emphasis added.]

7       7. Atossa materially altered the design of its ForeCYTE Breast Health Test and the  
 8 MASCT, including altering the tests' Nipple Aspirate Fluid (NAF) specimen collection process.  
 9 As a result, Atossa was required to provide premarket notification to the FDA, and allow these  
 10 devices to undergo additional FDA review and Section 510(k) qualification before public  
 11 distribution. The Company, however, failed to contact the FDA after materially altering its  
 12 products, and misled investors regarding its compliance with applicable FDA rules and  
 13 regulations.

14       8. On February 25, 2013, the Company disclosed that on February 21, 2013, it had  
 15 received a warning letter from the FDA regarding its MASCT System and MASCT System  
 16 Collection Test (together, the "System"). Specifically, in the warning letter, the FDA alleged  
 17 that "the Company changed the System in a manner that requires submission of an additional  
 18 510(k) notification to the FDA" and the letter also raised "certain issues with respect to the  
 19 Company's marketing of the System and the Company's compliance with FDA Good  
 20 Manufacturing Practices (cGMP) regulations, among other matters."

21       9. On this news, Atossa shares declined \$0.3869 per share or nearly 5.6%, to close at  
 22 \$6.54 per share on February 25, 2013.

23       10. On October 4, 2013, after the market closed, the Company announced "a  
 24 voluntary recall to remove the ForeCYTE Breast Health Test and the Mammary Aspiration

Specimen Cytology Test (MASCT) device from the market" after receiving a warning letter from the FDA.

3        11. On this news, Atossa shares declined \$2.47 per share, or more than 46%, to close  
4 at \$2.85 per share on October 7, 2013.

5       12. As further detailed below, during the Class Period, Defendants made false and/or  
6 misleading statements, as well as failed to disclose material adverse facts about Atossa's  
7 business and financial condition. Specifically, Defendants made false and/or misleading  
8 statements and/or failed to disclose to Atossa investors that: (1) the Company was required, but  
9 failed, to submit an additional 510(k) notification to obtain necessary FDA clearance as it made  
10 material changes to the Nipple Aspirate Fluid specimen collection process; (2) the Company  
11 improperly marketed these devices by using certain promotional claims to market the ForeCYTE  
12 Breast Health Test and the MASCT device; (3) the Company was in violation of FDA Good  
13 Manufacturing Practices regulations; and (4) as a result of the foregoing, Atossa's statements  
14 were materially false and misleading at all relevant times.  
15

16       13. As a result of Defendants' wrongful acts and omissions, and the precipitous  
17 decline in the market value of the Company's common stock, Plaintiff and other Class members  
18 have suffered significant losses and damages.

## **JURISDICTION AND VENUE**

21       14. The claims asserted herein arise under and pursuant to §§11, 12(a)(2) and 15 of  
22 the 1933 Act [15 U.S.C. §§77k and 77o], and §§10(b) and 20(a) of the Exchange Act [15 U.S.C.  
23 §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-  
24 5].

1       15. This Court has jurisdiction over the subject matter of this action pursuant to 28  
2 U.S.C. §1331, §22 of the 1933 Act, and §27 of the Exchange Act.

3       16. Venue is proper in this District pursuant to 28 U.S.C. § 1331(b) because  
4 defendants maintain an office in this District, and many of the acts and omissions complained of  
5 herein occurred in substantial part in this District.

6       17. In connection with the acts, conduct and other wrongs alleged in this Complaint,  
7 defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,  
8 including but not limited to, the United States mail, interstate telephone communications and the  
9 facilities of a national securities exchange.  
10

#### PARTIES

12       18. Plaintiff, as set forth in the attached Certification, purchased Atossa shares at  
13 artificially inflated prices during the Class Period and has been damaged upon the issuance of the  
14 alleged corrective disclosures.

15       19. Defendant Atossa is a Delaware corporation with principal executive offices  
16 located at 4105 East Madison Street, Suite 320, Seattle, Washington 98112. Atossa's common  
17 stock trades on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "ATOS."

18       20. Defendant Christopher Benjamin ("Benjamin") was the interim Chief Financial  
19 Officer of Atossa through January 3, 2013. Benjamin signed the false and misleading  
20 Registration Statement.

22       21. Defendant Kyle Guse ("Guse") has been the Chief Financial Officer, General  
23 Counsel and Secretary of Atossa since January 4, 2013.

1       22. Defendant Steven C. Quay (“Quay”) is, and was at all relevant times, the  
2 Chairman, President, and Chief Executive Officer of Atossa. Quay signed the false and  
3 misleading Registration Statement.

4       23. Defendant Shu-Chih Chen (“Chen”) serves as a director and Chief Scientific  
5 Officer of Atossa. Chen signed or authorized the signing of the false and misleading Registration  
6 Statement.

7       24. Defendant John Barnhart (“Barnhart”) served as a director of Atossa. Barnhart  
8 signed or authorized the signing of the false and misleading Registration Statement.

9       25. Defendant Stephen J. Galli (“Galli”) serves as a director of Atossa. Galli signed or  
10 authorized the signing of the false and misleading Registration Statement.

11       26. Defendant Alexander Cross (“Cross”) serves as a director of Atossa. Cross signed  
12 or authorized the signing of the false and misleading Registration Statement.

13       27. Defendant H. Lawrence Remmel (“Remmel”) serves as a director of Atossa.  
14 Remmel signed or authorized the signing of the false and misleading Registration Statement.

15       28. The defendants named in ¶¶ 20-27 above are sometimes referred to herein as the  
16 “Individual Defendants.”

17       29. Defendant Dawson James Securities, Inc. (“Dawson”) was an underwriter of the  
18 Company’s IPO and assisted in the preparation and dissemination of Atossa’s IPO materials.

19       30. Defendant ViewTrade Securities, Inc. (“ViewTrade”) was an underwriter of the  
20 Company’s IPO and assisted in the preparation and dissemination of Atossa’s IPO materials.

21       31. Defendant Paulson Investment Company, Inc. (“Paulson”) was an underwriter of  
22 the Company’s IPO and assisted in the preparation and dissemination of Atossa’s IPO materials.

32. The defendants named in ¶¶ 29-31 above are sometimes referred to herein as the "Underwriter Defendants."

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

33. Atossa is a healthcare company focused on the prevention of breast cancer through the commercialization of diagnostic medical devices and laboratory developed tests that can detect precursors to breast cancer, and through the research, development, and ultimate commercialization of treatments for pre-cancerous lesions and ductal carcinoma in situ. The Company's leading diagnostic test, the ForeCYTE Breast Health Test, consists of a patented medical device that can collect fluid samples from the breast milk ducts.

**Defendants' Materially False and Misleading Statements  
Made in Connection with the IPO and Issued During the Class Period**

34. On or about November 6, 2012, Atossa filed with the SEC a Form S-1/A Registration Statement (the “Registration Statement”), which would later be utilized for the IPO, and which incorporated a prospectus to be used in connection with the offer and sale of Atossa shares. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations governing its preparation.

35. The Registration Statement was signed by Defendants Quay, Benjamin, Barnhart, Cross, Chen, Galli and Remmel. Defendants Dawson, ViewTrade and Paulson served as the underwriters of the IPO.

36. On or about November 9, 2012, Atossa filed the final version of the public offering prospectus for the IPO, which forms part of the Registration Statement that became

1 effective on November 8, 2012 (collectively, the "Offering Documents"). The Prospectus  
 2 solicited investors for an IPO of 800,000 shares of Atossa common stock at a price of \$5.00 per  
 3 share, for proceeds, before expenses, to the Company of approximately \$3,720,000.

4       37. The Offering Documents represented the following in relevant part:

5       In December 2011, we began limited marketing of the ForeCYTE Test to  
 6 physicians, primarily obstetric-gynecologists, as well as breast health and  
 7 mammography clinics, for use in conjunction with other health screening  
 8 examinations, including annual physical examinations and regularly scheduled  
 9 cervical Pap smears and mammograms. We are establishing relationships with  
 10 breast cancer centers to provide the ArgusCYTE Test to their patients. As of  
 11 September 30, 2012, we had one person involved in sales.

12                   \*\*\*

13       The ForeCYTE Breast Health Test

14       The ForeCYTE Test uses the patented, FDA-cleared MASCT System medical  
 15 device for the collection, shipment and clinical laboratory analysis of NAF. The  
 16 ForeCYTE test involves cytopathology and five biomarkers of hyperplasia and  
 17 one biomarker of sample integrity and has been validated to CLIA standards. The  
 18 product components of the MASCT System consist of a reusable hand-held pump  
 19 for the collection of NAF, single-use patient kits that include two NAF sample  
 20 collection tools per kit, and shipment boxes for the transportation of NAF samples  
 21 to the National Reference Laboratory for Breast Health, our wholly-owned,  
 22 CLIA-certified specialized cytology and molecular diagnostics laboratory in  
 23 Seattle, Washington. Through our laboratory we provide the ForeCYTE Test,  
 24 which consists of receiving and accessioning the two NAF samples from each  
 25 patient, preparing routine and immunohistochemistry, or IHC, staining of slides  
 26 from the NAF samples, and generating a report of the findings. The NAF is  
 analyzed by microscopy for cytological abnormalities and by a patent-pending  
 IHC staining technique for five biomarkers of hyperplasia and a sample integrity  
 marker.

27                   \*\*\*

28       Most Class I devices, including the laboratory staining kits and reagents the  
 29 Company uses, and some Class II devices are exempted by regulation from the  
 30 510(k) clearance requirement and can be marketed without prior authorization  
 31 from FDA. Class I and Class II devices that have not been so exempted are  
 32 eligible for marketing through the 510(k) clearance pathway. By contrast, devices  
 33 placed in Class III generally require premarket approval, or PMA, approval prior  
 34 to commercial marketing. To obtain 510(k) clearance for a medical device, an  
 35 applicant must submit a premarket notification to the FDA demonstrating that the

device is “substantially equivalent” to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. In the case of the MASCT System, a clinical trial was conducted. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more. After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or (if the device as modified is not substantially equivalent to a legally marketed predicate device) PMA approval. While the determination as to whether new authorization is needed is initially left to the manufacturer, the FDA may review this determination and evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

\*\*\*

The Company and its contract manufacturers, specification developers and suppliers are also required to manufacture the MASCT and Microcatheter Systems in compliance with current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes the Company or any of its contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down the Company’s manufacturing operations, require recall of the MASCT System, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against the Company or its officers or other employees. Any such action by the FDA would have a material adverse effect on the Company’s business.

38. On December 20, 2012, the Company issued a press release announcing its financial results for the second quarter ended September 30, 2012. For the quarter, the Company

1 reported a net loss of \$1,143,382, or \$0.10 diluted loss per share LPS and revenue of \$105,576,  
 2 as compared to net loss of \$1,272,680, or \$0.11 diluted LPS, for the same period a year ago  
 3

4       39. On December 21, 2012, the Company filed a quarterly report for the period ended  
 5 September 30, 2012 on a Form 10-Q with the SEC, which was signed by, Defendants Quay and  
 6 Benjamin, and reiterated the Company's previously announced financial results and financial  
 7 position. In addition, the Form 10-Q contained signed certifications pursuant to the Sarbanes-  
 8 Oxley Act of 2002 ("SOX") by Defendants Quay and Benjamin, stating that the financial  
 9 information contained in the Form 10-Q was accurate and disclosed any material changes to the  
 10 Company's internal control over financial reporting.

11       40. On February 25, 2013, the Company issued a press release disclosing that it had  
 12 "received a Warning Letter ("Letter") from the FDA regarding its Mammary Aspirate Specimen  
 13 Cytology Test (MASCT) System and MASCT System Collection Test (together, the  
 14 "System.")." The press release stated the following in relevant part:

15       The Letter arises from certain FDA findings during a July 2012 inspection, to  
 16 which the Company responded in August 2012, explaining why the Company  
 17 believed it was in compliance with applicable regulations and/or was  
 18 implementing changes responsive to the findings of the FDA inspection. FDA  
 19 alleges in the Letter that following 510(k) clearance the Company changed the  
 20 System in a manner that requires submission of an additional 510(k) notification  
 21 to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in  
 22 the original 510(k) submission stated that the user must "Wash the collection  
 23 membrane with fixative solution into the collection vial..." and the current IFU  
 24 states "...apply one spray of Saccomanno's Fixative to the collection  
 25 membrane..." and that "this change fixes the NAF specimen to the filter paper  
 26 rather than washing it into a collection vial." At the time that the changes were  
 made the Company determined that a new 510(k) was not required in accordance  
 with the FDA's guidance document entitled, "Deciding When to Submit a 510(k)  
 for a Change to an Existing Device."

The Letter also raises certain issues with respect to the Company's marketing of  
 the System and the Company's compliance with FDA Good Manufacturing  
 Practices (cGMP) regulations, among other matters.

1       The Company is committed to working with the FDA to resolve these issues in  
 2       the best interests of patients and their doctors. If the FDA does not agree with the  
 3       Company's position concerning clearance of the System, Atossa may be required  
 4       to submit and receive clearance of a new 510(k) notice for the current form of the  
 5       System or revert to marketing the System using the prior NAF processing method.  
 6       The Company has until March 14, 2013 to respond to the Letter and is currently  
 7       working to prepare that response. Among other things, the Company currently  
 8       expects that the response will explain why the Company believes that the System  
 9       in its current form has been and continues to be appropriately marketed under a  
 10      cleared 510(k) premarket notification, and why it is in substantial compliance  
 11      with applicable regulations, including cGMP.

12      41.     On this news, Atossa shares declined \$0.3869 per share or nearly 5.6%, to close at  
 13      \$6.54 per share on February 25, 2013.

14      42.     On March 28, 2013, the Company filed an annual report for the year ended  
 15      December 31, 2012 on a Form 10-K with the SEC, which was signed by, Defendants Quay,  
 16      Guse, Barnhart, Chen, Cross, Galli and Remmel. For the year, the Company reported net loss of  
 17      \$5,079,851, or \$0.41 diluted LPS and revenue of \$481,842, as compared to net loss of  
 18      \$3,442,269, or \$0.38 diluted LPS and revenue of \$1,500 for the same period a year ago. In  
 19      addition, the Form 10-K contained signed certifications pursuant to SOX by Defendants Quay  
 20      and Guse, stating that the financial information contained in the Form 10-K was accurate and  
 21      disclosed any material changes to the Company's internal control over financial reporting.

22      43.     The Form 10-K represented the following in relevant part:

#### 23           The ForeCYTE Breast Health Test

24      The ForeCYTE Test uses the patented, FDA-cleared MASCT System medical  
 25      device for the collection, shipment and clinical laboratory analysis of NAF. The  
 26      ForeCYTE test involves cytopathology and five biomarkers of hyperplasia and  
 27      one biomarker of sample integrity and has been validated to CLIA standards. The  
 28      product components of the MASCT System consist of a reusable hand-held pump  
 29      for the collection of NAF, single-use patient kits that include two NAF sample  
 30      collection tools per kit, and shipment boxes for the transportation of NAF samples  
 31      to the National Reference Laboratory for Breast Health, our wholly-owned,  
 32      CLIA-certified specialized cytology and molecular diagnostics laboratory in

1 Seattle, Washington. Through our laboratory we provide the ForeCYTE Test,  
2 which consists of receiving and accessioning the two NAF samples from each  
3 patient, preparing routine and immunohistochemistry, or IHC, staining of slides  
4 from the NAF samples, and generating a report of the findings. The NAF is  
analyzed by microscopy for cytological abnormalities and by a patent-pending  
IHC staining technique for five biomarkers of hyperplasia and a sample integrity  
marker.

5 44. On May 15, 2013, the Company filed a quarterly report for the first quarter ended  
6 March 31, 2013 on a Form 10-Q with the SEC, which was signed by, Defendants Quay and  
7 Guse. For the quarter, the Company reported a net loss of \$1,941,440, or \$0.14 diluted LPS and  
8 revenue of \$182,670, as compared to a net loss of \$1,062,918, or \$0.09 diluted LPS and revenue  
9 of \$54,713 for the same period a year ago. In addition, the Form 10-Q contained signed  
10 certifications pursuant to SOX by Defendants Quay and Guse, stating that the financial  
11 information contained in the Form 10-Q was accurate and disclosed any material changes to the  
12 Company's internal control over financial reporting.  
13

14 45. On August 14, 2013, the Company filed an annual report for the second quarter  
15 ended June 30, 2013 on a Form 10-Q with the SEC, which was signed by, Defendants Quay and  
16 Guse. For the quarter, the Company reported a net loss of \$2,583,699, or \$0.17 diluted LPS and  
17 revenue of \$326,078, as compared to a net loss of \$1,167,948, or \$0.10 diluted LPS and revenue  
18 of \$223,097 for the same period a year ago. In addition, the Form 10-Q contained signed  
19 certifications pursuant to SOX by Defendants Quay and Guse, stating that the financial  
20 information contained in the Form 10-Q was accurate and disclosed any material changes to the  
21 Company's internal control over financial reporting.  
22

23 46. The statements referenced above were materially false and/or misleading because  
24 they misrepresented and failed to disclose the following adverse facts, which were known to  
25 Defendants or recklessly disregarded by them, including that: (1) the Company was required, but  
26

failed, to submit an additional 510(k) notification to obtain necessary FDA clearance as it made material changes to the Nipple Aspirate Fluid specimen collection process; (2) the Company improperly marketed these devices by using certain promotional claims to market the ForeCYTE Breast Health Test and the MASCT device; (3) the Company was in violation of FDA Good Manufacturing Practices regulations; and (4) as a result of the foregoing, Atossa's statements were materially false and misleading at all relevant times.

## **THE TRUTH EMERGES**

47. On October 4, 2013, after the market closed, the Company disclosed the following in relevant part:

On October 4, 2013 Atossa Genetics Inc. (NASDAQ: ATOS) initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test (MASCT) device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with Atossa's distributors and the remaining quantities are at customer sites across the United States. Distributors and customers should stop using affected products and return them to Atossa immediately.

Atossa is removing the ForeCYTE Breast Health Test and the MASCT device from the market to address concerns raised by the U.S. Food and Drug Administration (FDA) in a warning letter received by Atossa in February 2013. The FDA raised concerns about (1) the current instructions for use (IFU); (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the Nipple Aspirate Fluid (NAF) specimen collection process identified in the current IFU. Atossa will remove existing product from the market until FDA's concerns are addressed.

The MASCT device has been cleared by the FDA for use as a sample collection device, with the provision that the fluid collected using this device can be used to determine and/or differentiate between normal, pre-cancerous, and cancerous cells. The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, the ForeCYTE Breast Health Test has not been cleared or approved by the FDA for any indication. The ForeCYTE Breast Health Test and the MASCT device are not a replacement for screening mammograms, diagnostic imaging tests, or biopsies. Patients should follow the recommendations and instructions of their physician with respect to breast cancer screening and diagnosis.

To date, Atossa is unaware of any adverse incidents or injuries associated with the use of the ForeCYTE Breast Health test and the MASCT device or the processing method currently identified in the IFU. Additionally, Atossa is unaware of any risk to health or injury for clinicians or the patient population that have used these devices. However, these devices may produce false positive or false negative results. Although not cleared or intended for this use, if these devices are used as a substitute for recommended screening or diagnosis of breast cancer, FDA is concerned that patients may choose to forgo recommended mammograms and necessary biopsies.

48. On this news, Atossa shares declined \$2.47 per share, or more than 46%, to close at \$2.85 per share on October 7, 2013.

#### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

49. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons or entities who acquired Atossa shares during the Class Period and/or pursuant or traceable to the Company's false and misleading Registration Statement for its IPO, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Atossa, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Individual Defendants have or had a controlling interest.

50. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Atossa shares were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

51. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

1       52. Plaintiff will fairly and adequately protect the interests of the members of the  
 2 Class and has retained counsel competent and experienced in class and securities litigation.  
 3 Plaintiff has no interests antagonistic to or in conflict with those of the Class.

4       53. Common questions of law and fact exist as to all members of the Class and  
 5 predominate over any questions solely affecting individual members of the Class. Among the  
 6 questions of law and fact common to the Class are:

- 7             • whether the 1933 Act and/or the Exchange Act were violated by defendants'  
  8 acts as alleged herein;
- 9             • whether statements made by defendants to the investing public during the  
 10 Class Period misrepresented material facts about the financial condition,  
   business, and prospects of Atossa;
- 11            • whether defendants' public statements to the investing public during the Class  
 12 Period omitted material facts necessary to make the statements made, in light  
   of the circumstances under which they were made, not misleading;
- 13            • whether the defendants caused Atossa to issue false and misleading financial  
 14 statements during the Class Period;
- 15            • whether defendants acted knowingly or recklessly in issuing false and  
 16 misleading financial statements;
- 17            • whether the prices of Atossa shares during the Class Period were artificially  
   inflated because of the defendants' conduct complained of herein; and
- 18            • whether the members of the Class have sustained damages and, if so, what is  
 19 the proper measure of damages.

20       54. A class action is superior to all other available methods for the fair and efficient  
 21 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as  
 22 the damages suffered by individual Class members may be relatively small, the expense and  
 23 burden of individual litigation make it impossible for members of the Class to individually  
 24 redress the wrongs done to them. There will be no difficulty in the management of this action as  
 25 a class action.

55. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Atossa shares met the requirements for listing, and were listed and actively traded on the NASDAQ Global Select Market, a highly efficient and automated market;
  - As a public issuer, Atossa filed periodic public reports with the SEC and the NASDAQ;
  - Atossa regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
  - Atossa was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

56. Based on the foregoing, the market for Atossa shares promptly digested current information regarding Atossa from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

**COUNT I**

**For Violation of Section 11 of the 1933 Act  
(Against All Defendants)**

57. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein, except as set forth below in Paragraph 59.

58. This Count is brought pursuant to §11 of the 1933 Act, 15 U.S.C. §§77k, on behalf of the Class, against all defendants.

59. This Count does not sound in fraud. All of the preceding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count. Plaintiff does not

1 intent with respect to this Count, insofar as scienter or fraudulent intent are not elements of a §11  
2 claim.

3       60.      The Registration Statement for the IPO was inaccurate and misleading, contained  
4 untrue statements of material facts, omitted to state other facts necessary in order to make the  
5 statements not misleading, and omitted to state material facts required to be stated therein.

6       61.      Atossa is the registrant for the IPO. The other defendants named herein were  
7 responsible for the contents and dissemination of the Registration Statement.

8       62.      As the issuer of the shares, Atossa is strictly liable to Plaintiff and the Class for  
9 any misstatements or omissions in the Registration Statement.

10       63.     None of the defendants named herein made a reasonable investigation or  
11 possessed reasonable grounds for the belief that the statements contained in the Registration  
12 Statement were true, and/or without omissions of any material facts, were not misleading.

13       64.     By reason of the conduct alleged herein, each defendant violated, and/or  
14 controlled a person who violated, §11 of the 1933 Act.

15       65.     Plaintiff acquired Atossa shares pursuant and/or traceable to the Registration  
16 Statement for the IPO.

17       66.     Plaintiff and the Class have sustained damages. The value of Atossa stock has  
18 declined substantially subsequent to and due to defendants' violations.

19       67.     At the time of his purchases of Atossa shares, Plaintiff and the other members of  
20 the Class were without knowledge of the facts concerning the wrongful conduct alleged herein  
21 and could not have reasonably discovered those facts prior to October 4, 2013. Less than one  
22 year has elapsed from the time that Plaintiff discovered or reasonably could have discovered the  
23 facts upon which this complaint is based, to the time that Plaintiff filed this complaint. Less than  
24

1 three years elapsed between the time that the securities upon which this Count is brought were  
 2 offered to the public, and the time Plaintiff filed this complaint.

3 **COUNT II**

4 **For Violation of Section 12(a)(2) of the Securities Act  
 (Against All Defendants)**

5 68. Plaintiff repeats and realleges each and every allegation contained above as if  
 6 fully set forth herein, except as set forth below in Paragraph 70.

7 69. Defendants named in this Count were sellers, offerors, underwriters and/or  
 8 solicitors of sales of the Atossa common stock offering pursuant to the Prospectus.

9 70. This Count does not sound in fraud. All of the preceding allegations of fraud or  
 10 fraudulent conduct and/or motive are specifically excluded from this Count. Plaintiff does not  
 11 allege that the Individual Defendants, or the Underwriter Defendants had scienter or fraudulent  
 12 intent with respect to this Count, insofar as scienter or fraudulent intent are not elements of a §12  
 13 claim.

14 71. The Prospectus contained untrue statements of material facts, omitted to state  
 15 other facts necessary to make the statements made not misleading, and concealed and failed to  
 16 disclose material facts. The actions of solicitation by Defendants named in this Count included  
 17 participating in the preparation of the false and misleading Prospectus.

18 72. Defendants named in this Count owed, to the purchasers of Atossa common stock  
 19 which were sold in the Company's IPO, the duty to make a reasonable and diligent investigation  
 20 of the statements contained in the Prospectus, to ensure that such statements were true and that  
 21 there was no omission to state a material fact required to be stated in order to make the  
 22 statements contained therein not misleading. The Defendants named in this Count knew of, or in  
 23 the exercise of reasonable care should have known of, the misstatements and omissions  
 24

contained in the IPO materials as set forth above.

73. Plaintiff and other members of the Class purchased or otherwise acquired Atossa common stock pursuant to and traceable to the defective Prospectus. Plaintiff did not know, and in the exercise of reasonable diligence could not have known, of the untruths and omissions.

74. Plaintiff, individually and representatively, hereby offers to tender to the Defendants named in this Count those shares which Plaintiff and other Class members continue to own, on behalf of all members of the Class who continue to own such common stock, in return for the considerations paid for those shares, together with interest thereon.

75. By reason of the conduct alleged herein, the Defendants named in this Count violated, and/or controlled a person who violated, section 12(a)(2) of the Securities Act. Accordingly, Plaintiff and members of the Class who hold Atossa shares purchased pursuant and/or traceable to the IPO have the right to rescind and recover the consideration paid for their Atossa shares and, hereby elect to rescind and tender their Atossa shares to the Defendants named in this Count. Plaintiff and Class members who have sold their Atossa shares are entitled to rescissionary damages.

76. Less than three years elapsed from the time that the shares upon which this Count IV is brought were sold to the public to the time of the filing of this action. Less than one year elapsed from the time when Plaintiff discovered or reasonably could have discovered the facts upon which this Count is based to the time of the filing of this action.

### COUNT III

**For Violation of Section 15 of the 1933 Act  
(Against Atossa and the Individual Defendants)**

77. Plaintiff repeats and realleges each and every allegation contained above, excluding all allegations that contain facts necessary to prove any elements not required to state a

Section 15 claim, including without limitation, scienter.

78. This Count is brought pursuant to §15 of the 1933 Act against Atossa and the Individual Defendants.

79. This Count does not sound in fraud. All of the preceding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count. Plaintiff does not allege that Individual Defendants had scienter or fraudulent intent with respect to this Count, insofar as scienter or fraudulent intent are not elements of a §15 claim.

80. The Individual Defendants each were control persons of Atossa by virtue of their positions as a director and/or senior officer of Atossa. The Individual Defendants each had a series of direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Atossa. The Individual Defendants controlled Atossa.

99. Defendants each were culpable participants in the violations of §11 of the 1933 Act alleged in Count I above, based on their having signed or authorized the signing of the Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

**COUNT IV**

**For Violations of Section 10(b) and Rule 10b-5 Promulgated Thereunder  
(Against Atossa and Quay, Guse and Benjamin)**

81. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

82. This Count is asserted against Atossa, Quay, Guse and Benjamin and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

1       83. During the Class Period, Atossa, Quay, Guse and Benjamin, individually and in  
 2 concert, directly or indirectly, disseminated or approved the false statements specified above,  
 3 which they knew or deliberately disregarded were misleading in that they contained  
 4 misrepresentations and failed to disclose material facts necessary in order to make the statements  
 5 made, in light of the circumstances under which they were made, not misleading.

6       84. Atossa, Quay, Guse and Benjamin violated §10(b) of the 1934 Act and Rule 10b-  
 7 5 in that they:

- 8             • employed devices, schemes and artifices to defraud;
- 9             • made untrue statements of material facts or omitted to state material facts  
 10 necessary in order to make the statements made, in light of the circumstances  
 11 under which they were made, not misleading; or
- 12             • engaged in acts, practices and a course of business that operated as a fraud or  
 13 deceit upon plaintiff and others similarly situated in connection with their  
 purchases of Atossa common stock during the Class Period.

14       85. Atossa, Quay, Guse and Benjamin acted with scienter in that they knew that the  
 15 public documents and statements issued or disseminated in the name of Atossa were materially  
 16 false and misleading; knew that such statements or documents would be issued or disseminated  
 17 to the investing public; and knowingly and substantially participated, or acquiesced in the  
 18 issuance or dissemination of such statements or documents as primary violations of the securities  
 19 laws. These defendants by virtue of their receipt of information reflecting the true facts of  
 20 Atossa, their control over, and/or receipt and/or modification of Atossa's allegedly materially  
 21 misleading statements, and/or their associations with the Company which made them privy to  
 22 confidential proprietary information concerning Atossa, participated in the fraudulent scheme  
 23 alleged herein.

1       86. Quay, Guse and Benjamin, who are the senior officers of the Company, had actual  
 2 knowledge of the material omissions and/or the falsity of the material statements set forth above,  
 3 and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted  
 4 with reckless disregard for the truth when they failed to ascertain and disclose the true facts in  
 5 the statements made by them or other Atossa personnel to members of the investing public,  
 6 including Plaintiff and the Class.

7       87. As a result of the foregoing, the market price of Atossa common stock was  
 8 artificially inflated during the Class Period. In ignorance of the falsity of the statements by  
 9 Atossa, Quay, Guse and Benjamin, Plaintiff and the other members of the Class relied on the  
 10 statements described above and/or the integrity of the market price of Atossa securities during  
 11 the Class Period in purchasing Atossa common stock at prices that were artificially inflated as a  
 12 result of Atossa, Quay, Guse and Benjamin's false and misleading statements.

14       88. Had Plaintiff and the other members of the Class been aware that the market price  
 15 of Atossa common stock had been artificially and falsely inflated by Atossa, Quay, Guse and  
 16 Benjamin's misleading statements and by the material adverse information which Atossa, Quay,  
 17 Guse and Benjamin did not disclose, they would not have purchased Atossa common stock at the  
 18 artificially inflated prices that they did, or at all.

19       89. As a result of the wrongful conduct alleged herein, Plaintiff and other members of  
 20 the Class have suffered damages in an amount to be established at trial.

22       90. By reason of the foregoing, Atossa, Quay, Guse and Benjamin have violated  
 23 Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the  
 24 plaintiff and the other members of the Class for substantial damages which they suffered in  
 25 connection with their purchase of Atossa common stock during the Class Period.

## COUNT V

## **Violations of Section 20(a) of the Exchange Act (Against Quay, Guse and Benjamin)**

91. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

92. During the Class Period, Defendants Quay, Guse and Benjamin participated in the operation and management of Atossa, and conducted and participated, directly and indirectly, in the conduct of Atossa's business affairs. Because of their senior positions, they knew the adverse non-public information about Atossa's misstatement of compliance with applicable rules and regulations..

93. As officers and/or directors of a publicly owned company, Defendants Quay,  
Guse and Benjamin had a duty to disseminate accurate and truthful information with respect to  
Atossa's compliance with applicable rules and regulations, and to correct promptly any public  
statements issued by Atossa which had become materially false or misleading.

94. Because of their positions of control and authority as senior officers, Defendants Quay, Guse and Benjamin were able to, and did, control the contents of the various reports, press releases and public filings which Atossa disseminated in the marketplace during the Class Period concerning Atossa's compliance with applicable rules and regulations . Throughout the Class Period, Defendants Quay, Guse and Benjamin exercised their power and authority to cause Atossa to engage in the wrongful acts complained of herein. Defendants Quay, Guse and Benjamin therefore, were "controlling persons" of Atossa within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Atossa.

95. By reason of the above conduct, Defendants Quay, Guse and Benjamin are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Atossa.

## **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and,

D. Awarding such other and further relief as this Court may deem just and proper.

## **DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: October 10, 2013

**ZWERLING, SCHACHTER &  
ZWERLING, LLP**

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**Certification of Plaintiff  
Pursuant to Federal Securities Laws**

1. I, Nicholas Cook, make this declaration pursuant to Section 101 of the Private Securities Litigation Reform Act of 1995 as required by Section 21D (a) (2) of Title I of the Securities Exchange Act of 1934.

2. I have reviewed a Complaint against Atossa Genetics, Inc. Corporation. ("Atossa"), and authorize a filing of a comparable complaint on my behalf.

3. I did not purchase my Atossa securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under Title I of the Securities Exchange Act of 1934.

4. I am willing to serve as a representative party on behalf of a class as set forth in the Complaint, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

5. To the best of my current knowledge, the attached sheet lists all of my purchases and sales in Atossa securities during the Class Period as specified in the Complaint.

6. During the three-year period preceding the date on which this certification is signed, I have not sought to serve as a representative party on behalf of a class under the federal securities laws, except as follows:

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

8. The matters stated in this declaration are true to the best of my current knowledge, information and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed October 8, 2013  
(Date)



(Signature)

Nicholas Cook  
(Type or Print Name)

### **Summary of Purchases and Sales**